

REMARKS

Upon entry of the above amendments, claims 1-5, 13-18, 23, 24, 26-40, 42, 44, 45, 52-57, 62, 63, 65-68, and 80-85 will be pending. No claims have been canceled by way of this amendment. Claims 1, 36, and 42 have been amended, and claims 80-85 have been added. Specifically, claims 1 and 36 have been amended to clarify that the electroporation-based methods of the invention employ compositions that "consist of" a pharmaceutically acceptable carrier and a photooxidizing agent. If the composition contains a plurality of different photosensitive agent species, at least one of the species will be a photooxidizing agent. Support for "pharmaceutically acceptable carrier" is found in the specification at page 13, lines 1-26. In claim 42, the term "about" has been added simply to conform with preferred terminology used in other pending claims reciting a value or range of values (e.g., claims 3, 4, 17, 18, 24, 56, 57, and 63).

Claims 80-85 have also been added, as the Action indicated that the invention of claims 29, 34, and 68 would be allowable if written in independent form. New claims 80, 84, and 85 represent claims 29, 34, and 68, respectively, written in independent form. New claims 81 and 82, which depend from claim 80, correspond to claims 27 and 28, and new claim 83 corresponds to claim 13.

Applicants introduce the amendments above for the sole purpose of facilitating prosecution, and not for reasons related to patentability. Also, these amendments advance prosecution, or, alternatively, place the claims in better condition for appeal. Furthermore, these amendments add no new matter, do not require additional searching, and are fully supported by the specification and claims as originally filed. Accordingly, their entry at this stage is proper. For the record, Applicants also reserve the right to pursue subject matter no longer or not yet claimed in this or a related application.

Applicants request reconsideration of the application in light of the following remarks.

Rejection Under 35 U.S.C. § 102

Applicants respectfully traverse the rejection of claims 1-5, 13, 14, 17, 18, 23, 24, 26, 32, 33, 36-39, 42, 44-45, 52, 53, 56, 57, 62, 63, and 65 under 35 U.S.C. § 102(e) as allegedly anticipated by Walker, et al. (U.S. Pat. No. 6,041,252).

Applicants reiterate that the '252 patent markedly differs from Applicants' claimed invention because the '252 patent requires the delivery of cytotoxic agents using liposomes, whereas Applicants' claimed methods do not use liposomes. While Applicants disagree with the Examiner's interpretation of the transition "consisting essentially of" and the assertion that liposomes would not materially alter the compositions used in practicing the claimed methods, to advance prosecution Applicants have amended claims 1 and 36 to use the transition "consisting of", thereby obviating the basis of this rejection. The 35 U.S.C. § 102(e) rejection should thus be withdrawn.

Before moving on, however, Applicants wish to clarify that the passage of their specification cited in the Action, i.e., page 13, line 24, should not be read to mean that compositions with and without liposomes are not materially different. As is well known in the art, and as reflected in the '252 patent, liposomes can fundamentally change the nature and function of a given composition, for example, by sequestering the active agents from cells and serum components. As a result, liposomes can be used, for example, to alter the half-life, distribution, and bioavailability of compounds encapsulated therein. Accordingly, liposome-containing formulations are, by nature, materially different from formulations that do not include liposomes. That, however, does not mean that a broad method can not employ formulations that include liposomes and those that do not.

Rejection Under 35 U.S.C. § 103

Applicants also respectfully traverse the 35 U.S.C. § 103(a) rejection of claims 27-28, 35

and 66-67 over the '252 patent, and the 35 U.S.C. § 103(a) rejection of claims 15, 16, 31, and 54-55 over the '252 patent in view of Kennedy, et al. (U.S. Pat. No. 5,079,262).

To establish a prima facie case of obviousness based on one or more references, the PTO has the burden of providing a convincing line of reasoning as to why the artisan would have made the proposed modification, a reasonable expectation of success, and the presence, explicitly or by suggestion, of all elements (or steps) of the rejected claim. See MPEP 2142, et seq. To make this showing, the Office must provide an explanation of why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modifications, and how the claimed invention would have been obvious in light of the cited literature.

Applying this standard, the '252 patent, alone or in combination with the '262 patent, does not render Applicants' invention obvious. First, as explained above, the '252 patent requires the use of liposomes to encapsulate active compounds. This requirement means that the '252 patent does not suggest Applicants' claimed methods. As such, the 35 U.S.C. § 103(a) rejections of claims 27-28, 35, and 66-67 should be withdrawn.

Turning to the rejection premised on the combination of the '252 and '262 patents, it is important to note that the '262 patent does not mention "liposome," "lipid," or "vesicle." Moreover, unlike the compounds of the '252 patent, the compounds disclosed in the '262 patent are delivered as precursors that are converted to active agents after cell uptake. Moreover, the compounds of the '262 patent are selectively taken up by cells to be treated. Thus, in the '252 patent, liposomes provide for targeting delivery of active agents to desired cells, whereas in the '262 patent, targeting is provided by virtue of the target cells selectively taking up the precursor compounds. Given these differences, the ordinarily skilled artisan would have no motivation to combine the disclosures of the '252 and '262 patents. Indeed, these discordant disclosures argue away from any such combination. This 35 U.S.C. § 103(a) rejection should be withdrawn for this reason alone.

Even if combined, however, the '252 and '262 patents do not suggest Applicants' invention, as the compositions resulting from such an unwarranted combination would include

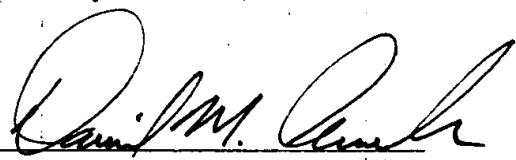
liposome-encapsulated precursor compounds. As explained above, Applicants' claimed methods, either before or after entry of the amendment above, do not employ liposome-encapsulated compositions. Accordingly, the '252 patent, even if combined with the '262 patent, does not teach or suggest every element of Applicants' claims. Similarly, the '252 patent, alone or in combination with the '262 patent, provides no reasonable expectation of success with regard to the instant invention. Because the Action fails to establish a prima facie of obviousness, Applicants respectfully submit that the 35 U.S.C. § 103(a) rejections should be withdrawn.

CONCLUSION

Applicants believe that all claims are in condition for allowance and respectfully request Notice thereof. Should any issues or questions remain, the Examiner is encouraged to telephone the undersigned at 858.350.9690 so that they may be promptly resolved without the need for an additional formal action and response thereto.

Dated: 17 APR 2004

Respectfully submitted,

By: 
Daniel M. Chambers
Attorney for Applicants
BioTechnology Law Group
Reg. No. 34,561